



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0018]

Agency Information Collection Activities; Proposed Collection; Comment Request; Healthcare Professional Survey of Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Healthcare Professional Survey of Prescription Drug Promotion. This survey is designed to explore the opinions and perceptions of physicians, nurse practitioners, and physician assistants with regard to the promotion of prescription drugs to consumers and healthcare providers.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Healthcare Professional Survey of Prescription Drug Promotion--(OMB Control Number 0910--New)

I. Regulatory Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information.

Section 903(d)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

II. Description

The rise of direct-to-consumer (DTC) drug advertising and prescription drug promotion has affected healthcare professionals in a number of ways. First, healthcare professionals regularly encounter patients who have been exposed to DTC ads. Second, healthcare professionals also see and hear such ads directly as mass media consumers themselves. Since clarification of the adequate provision requirement for prescription drug broadcast ads in 1997, FDA has faced numerous questions about the influence of DTC pharmaceutical marketing because such advertising directly engages consumers and potentially affects interactions between patients and their physicians (Refs. 1 and 2). Those questions have grown more urgent with the

growth of DTC advertising in recent years (Refs. 3 and 4). In 2002, FDA considered this form of promotion sufficiently important as a force in the physician-patient interaction that they surveyed both patients and physicians regarding their perceptions of DTC advertising (Ref. 5). Now, nearly a decade later, there are critical reasons to return to the field to gather more evidence on the influence of DTC advertising in the examination room and on the relationships between healthcare professionals and patients.

One of the most noteworthy aspects of the current healthcare environment in 2011 is the role now played by various physician extenders. Naylor and Kurtzman (Ref. 6) recently noted that nurses are the single largest group of healthcare providers in the United States and they argue that nurse practitioners will play an increasingly vital role in primary care delivery. Similarly, physician assistants also bolster the ability of our healthcare system to offer some types of care at lower cost. The aforementioned 2002 FDA study did not include nurse practitioners or physician assistants in the sample; that study focused on general practitioners and specialists in several key areas targeted by DTC advertising. Murray and colleagues (Ref. 7) also conducted a large-scale survey of U.S. physicians regarding their perceptions of DTC advertising, but they also did not include nurse practitioners or physician assistants in their sample. Because DTC advertising likely affects daily interactions between patients and nurse practitioners and physician assistants--similar to the 2002 FDA study that suggested the influence of advertising on physicians' work lives--including these groups in the new sample will further understanding of DTC advertising in the healthcare system.

Another limitation of the 2002 FDA study was the extent to which the results were nationally representative. As FDA has acknowledged, the initial set of results as reported were applicable to survey respondents but were not weighted to reflect national statistics as to the age,

sex, and racial composition of the healthcare professional population. Similar to many types of surveys that have struggled in recent decades with declines in cooperation rates (Ref. 8), surveys of healthcare professionals in general often can benefit from weighting to reduce nonresponse bias. The current survey will include weighted responses from respondents that will reflect national demographic patterns.

Over the past decade, researchers have been able to better assess how DTC advertising has unfolded in the United States and determine the questions that warrant further survey work. For example, researchers have worried for a number of years that DTC advertising might produce adverse outcomes, such as clinically inappropriate patient requests for drugs or patient overestimation of the efficacy of advertised medications (Refs. 5, 7, 9, and 10). At the same time, the 2002 FDA survey found that roughly as many physicians thought DTC advertising had a positive effect on their practice as those who thought there had been a negative influence. Moreover, the 2002 FDA survey found that roughly a third of physicians surveyed thought that DTC advertising had essentially no influence on their practice. The question of whether a similar pattern will emerge now, despite the growth of DTC advertising, is a vital one. Furthermore, FDA will benefit from knowing more detail about the various types of perceived effects DTC advertising might have. For example, some healthcare professionals might be ambivalent rather than strongly in favor of or opposed to DTC advertising. In addition, with the proliferation of social media platforms, the emergence of online pharmaceutical marketing, and the evolution of office detailing practices (Refs. 11 and 12), FDA will benefit by knowing more about healthcare professionals' awareness of new and emerging drug promotion sites and practices. The proposed survey will address these issues.

III. Method Overview

We propose a nationally representative sample of healthcare professionals that will yield 2,000 responses from 500 general practitioners, 500 specialists, 500 nurse practitioners, and 500 physician assistants. Such a design will help to ensure our ability to discuss not only healthcare professional perceptions generally but also to assess potential variation between different types of healthcare professionals. This sample will be recruited from a national Internet healthcare professional panel that includes over 70,000 individuals originating from the American Medical Association master file and other medical organizations. Because there are not enough individuals in this panel to satisfy the needs of the proposed project, nurse practitioners and physician assistants will be specially recruited from relevant professional organizations.

Healthcare providers are a difficult group to recruit, and so several strategies will be put into place to achieve a high response rate. These include sending prenotification letters before online invitation, lengthening the data collection period to 8 weeks (from the more typical 4 weeks), tailoring contact materials, disclosing FDA sponsorship on survey materials, and conducting reminder telephone calls. Appropriate weighting will be applied to adjust for any survey nonresponse as well as any noncoverage or undersampling and oversampling resulting from the sample design.

Participants who agree to participate will answer questions online. The survey is expected to take no longer than 20 minutes. This will be a one-time (versus annual) data collection.

FDA estimates the burden of this collection of information as follows: The total respondent sample for this data collection is 2,025. We will sample 25 respondents for basic

programming pretesting and 2,000 respondents for the full study. We estimate the response burden to be 20 minutes, for a burden of 1,008 hours.

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Screeners	10,000	1	10,000	2/60	333
Pretest	25	1	25	20/60	8
Main Study	2,000	1	2,000	20/60	667
Total					1,008

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Fintor, L., "Direct-to-Consumer Marketing: How Has It Fared?," Journal of the National Cancer Institute, 94, 329-331, 2002.

2. Palumbo, F.B. and C.D. Mullins, "The Development of Direct-to-Consumer Prescription Drug Advertising Regulations," Food and Drug Law Journal, 57, 423-443, 2002.

3. Curry, T.J., J. Jarosch, and S. Pacholok, "Are Direct to Consumer Advertisements of Prescription Drugs Educational? Comparing 1992 to 2002," Journal of Drug Education, 35, 2172-2232, 2005.

4. Government Accountability Office (GAO), "Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising, GAO-07-54, Washington, DC: GAO, November 16, 2006.

5. Aikin, K.J., J.L. Swasy, and A.C. Braman, "Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs," Washington, DC: Food and Drug Administration, November 19, 2004.

6. Naylor, M.D. and E.T. Kurtman, "The Role of Nurse Practitioners in Reinventing Primary Care," Health Affairs, 29, 893-899, 2010.

7. Murray, E., B. Lo, L. Pollack, et al., "Direct-to-Consumer Advertising: Physicians' Views of Its Effects on Quality of Care and the Doctor-Patient Relationship," Journal of the American Board of Family Practice, 16, 513-524, 2003.

8. Dey, E.L., "Working With Low Survey Response Rates: The Efficacy of Weighting Adjustments," Research in Higher Education, 38, 215-227, 1997.

9. Mintzes, B., M.L. Barer, R.L. Kravitz, et al., "Influence of Direct-to-Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Study," British Medical Journal, 324, 278-279, 2002.

10. Mitra, A., J. Swasy, and K. Aikin, "How Do Consumers Interpret Market Leadership Claims in Direct-to-Consumer Advertising of Prescription Drugs?," Advances in Consumer Research, 33, 381-387, 2006.

11. Donohue, J.M., M. Cevalco, and M.B. Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," New England Journal of Medicine, 357, 673-681, 2007.

12. Chew, L.D., T.S. O'Young, T.K. Hazlet, et al., "A Physician Survey of the Effect of Drug Sample Availability on Physician's Behavior," Journal of General Internal Medicine, 15, 478-483, 2000.

Dated: January 10, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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